WOODPECKER®

CURING LIGHT LED.G USER'S MANUAL

(Please read this manual before operating)

FDA CE

www.tuv.com ID 0000033514 TÜVRheinland

- Certified Management System
- EN ISO 9001
- EN ISO 13485

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

www.glwoodpecker.com

Content

1. Introduction

Guilin Woodpecker Medical Instrument Co., Ltd. is a high-tech enterprise in researching, developing, and producing dental equipment, and has a perfect quality assurance system, main products including ultrasonic scaler, curing light, micro motor, apex locator and ultrasurgery etc.

2. Principle and usage

2.1 LED.G adopts the principle of ray radiation to solidify the light-sensitive resin by shooting at it in a short time.

2.2 This product is used to restore teeth and solidify material for whitening teeth.

3. Structure and components

LED.G (dental) is composed mainly of high power LED, optical fiber and main unit. (Picture 1)

4. Technical specifications

4.1 Power supply: 24V~ 50Hz/60Hz

4.2 Applied part: optical fiber

4.3 Light source:

Blue light

Wave length: 420nm-480nm

Light intensity: 1000mW/cm^2~1200mW/cm^2

4.4 Working condition:

Environment temperature: 5℃ to 40℃

Relative humidity: ≤80%

Atmosphere pressure: 70kPa to 106kPa

4.5 Dimensions: 26mm×25mm×260mm

4.6 Net weight: 135g

4.7 Consumption power: ≤8W

4.8 Protection type against electrical shock: class Ⅱ

4.9 Protection against electrical shock: type B

4.10 Protection against harmful ingress of water or particular matter: ordinary equipment (IPX0)

4.11 Safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: not suitable under this condition.

4.12 Intermittent operation instrument: after work 200 seconds, stop 20 seconds, and then work 20 seconds, stop 20 seconds, work in the rule as above circularly.

5. Install and uninstall way

5.1 Connect the LED power supply line with the power (24V~) of dental unit. Tight the nylon thread to the fixation of the dental unit, then it will be available for operation.

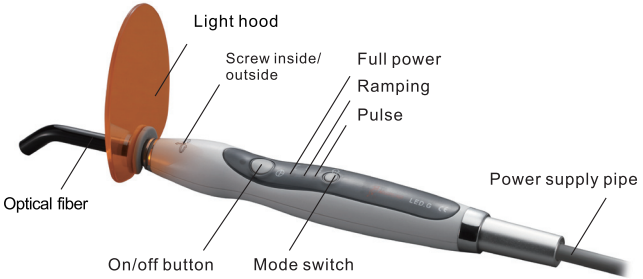
Notice:When installing the LED, be sure the power is cut off.

The two power wire should be a little longer than the nylon thread to keep the power wire safe.

5.2 Take off the red cap from the optical fiber and insert the metal part into the front of the built-in LED.G (Make sure to screw the fiber to the end by rotation).

5.3 Install the light hood as showed in picture 1.

5.4 Uninstall the LED, just reverse the procedure above.



Picture 1

6. Operation

You can choose one of three operation modes by pressing the mode switch button on the curing light.

6.1 Full power: the blue light radiates in full power.

6.2 Ramping: The blue light power increases stronger continually, after five seconds reaches to the highest power.
6.3 Pulse: The blue light works on the pulse condition. During the operation, aim blue solidification. The working time of all modes is ten seconds.

7. Precaution

7.1 During operation the light should be aimed straightly on the resin, to ensure solidification effectively.
7.2 Avoid aiming light at eyes directly.
①WARNING: If the curing light works for 40s continously, the temperature of the top of optical fiber may reach 56℃.
②WARNING: Do not modify this equipment without authorization of the manufacturer.

8. Contraindication

The heart disease patients, pregnant women and children should be cautious to use this equipment.

9. Maintenance

9.1 Only the optical fiber can be autoclaved under high temperature and pressure.

9.2 After operation each time, please shut off the power source and clean the optical fiber.

10. After service

From the date this equipment has been sold, base on the warranty card, we will repair this equipment free of charge if it has quality problems, please refer to the warranty card for the warranty period for units and parts.

11. Troubleshooting

Faulty	Possible cause	Solution
Non-indication Non-act.	1. The LED is not connected well with the power. 2. The power is off.	1. Check the connection of the LED and the power. 2. Make sure the power is on.
Light intensity insufficient.	1. Optical fiber isn't inserted well to the bottom. 2. The optical fiber has cracked. 3. There is resin remain on the surface of the optical fiber.	1. Install the optical fiber well. 2. Change the optical fiber. 3. Remove the resin.

If all the above solutions have been completed, the machine still can not work normally. Please contact our special repair shop or us.

12. Packing List

The components of the equipment are listed in the packing list.

13. Storage and transportation

13.1 This equipment should be handled carefully, kept away from shaking point, installed or stored at shadowy, dry, cool and ventilated places.

13.2 Don't store it together with articles that are combustible, poisonous, caustic and explosive.

13.3 This equipment should be stored in the environment where the relative humidity is ≤ 80%, the atmosphere pressure is 70kPa to 106kPa and the temperature is -10℃ to +55℃.

13.4 Excess impact or shake should be avoided during transportation.

13.5 Don't mix it with dangerous articles during transportation.

13.6 Keep it away from sun or snow or rain during transportation.

14. Environmental protection

There is not any harmful element in our product. It can be disposed according to the local laws.

15. Manufacturer's right

We reserve the rights to change the design of the equipment, the

technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

16. For technical data, please contact

EC REP Wellkang Ltd (www.CE-Marking.eu)
29 Harley St.,LONDON,W1G 9QR,UK

17. Symbol instruction

WOODPECKER® Trademark

Type B applied part

IPX0 Ordinary equipment

Consult the accompanying documents

Date of manufacture

Manufacturer

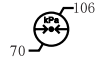
Used indoor only

Screw inside/ outside

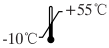
Class Ⅱ equipment

Appliance compliance WEEE directive

Recovery



Atmospheric pressure for storage



Temperature limitation

Humidity limitation

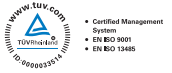
Keep dry

Handle with care

CE marked product

FDA marked product

EC REP Authorised Representative in the EUROPEAN COMMUNITY



Got the quality management system certification and CE certification issued by TüV Rheinland

18. Declaration of conformity

18.1 Product conforms to the following standards:

EN 60601-1:2006	EN 1041:2008
EN 60601-1-2:2007	EN ISO 14971:2009
EN 61000-3-2:2006	EN ISO 7405:2008
EN 61000-3-3:2008	EN ISO 17664:2004
EN 60601-1-4:1996	EN ISO 17665-1:2006
EN 60825-1:2007	EN ISO 10993-1:2009
EN 980:2008	EN ISO 10993-5:2009
ISO 9687:1993	EN ISO 10993-10:2010

18.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The model LED.G is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.G should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model LED.G uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model LED.G is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance & Declaration — electromagnetic immunity			
The model LED.G is intended for use in the electromagnetic environment specified below. The customer or the user of the model LED.G should assure that It is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T (>95% dip in U_T.) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model LED.G require continued operation during power mains interruptions, it is recommended that the model LED.G be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity

The model LED.G is intended for use in.the electromagnetic environment specified below. The customer or the user of the model LED.G should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	*3V* *3V/m*	Portable and mobile RF communications equipment should be used no closer to any part of the model LED.G, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and *d* Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur In the vicinity of equipment marked with the following symbol: 

NOTE I At 80 MHz end 800 MHz. the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model LED.G is used exceeds the applicable RF compliance level above, the models LED.G should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model LED.G.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the model LED.G

The model LED.G is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model LED.G can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model LED.G as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference Avoid using the device in high electromagnetic environment.

19. Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must take legal responsibilities.

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